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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/202,104

04/30/1999

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2481

7590

10/20/2003

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EXAMINER

LANDSMAN, ROBERT S

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 10/20/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/202,104

Applicant(s)

VAN LEENGOED ET AL.

Examiner

Robert Landsman

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1,4,5,8,9,11,12,15,21,23,72,74,75 and 78 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1,4,5,8,9,11,12,15,21,23,72,74,75 and 78 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 21
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Formal Matters

- A. Amendment F, filed 7/15/03, has been entered into the record.
- B. Claims 1, 4, 5, 8, 9, 11, 12, 15, 21, 23, 72, 74, 75 and 78 are pending and are the subject of this Office Action.
- C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Specification

- A. The objection to the specification has been withdrawn in view of Applicants' amendment to the first line to recite the priority information.
- B. The specification remain objected to since it is not in the proper arrangement. Applicants request that this objection be withdrawn until a notice of allowance is granted. However, the objection remains, but can be dealt with upon allowance. Though it is preferred that Applicants provide an amendment in their response to this Office Action.
- C. The objection to the specification regarding a missing abstract has been withdrawn in view of Applicants' submission of an abstract.

3. Claim Objections

- A. Claim 74 is objected to since the syntax can be improved by amending the phrase "A method for exerting agonistic IL-6 activity." Using the example on page 15, for example, the claim could be amended to recite, "A method of inducing proliferation of B9 cells..."
- B. Claim 75 is objected to since a "mixture" comprises more than one item.

Art Unit: 1647

4. Claim Rejections - 35 USC § 112, first paragraph – enablement

A. The rejection of all claims under 35 USC 112, first paragraph, regarding the breadth of claim 1 which recites “5 amino acids” has been withdrawn in view of Applicants’ amendment to claim 1 to recite that the peptide is at least 12 amino acids. Due to the short length of SEQ ID NO:11, testing all “12-mers” would not rise to the level of undue experimentation.

B. Claim 23 remains rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 4-5 of the Office Action dated 1/15/03. The claim recites a method for manufacturing a medicament. However, no process steps have been recited in the claim, nor have Applicants demonstrated that the claimed compound will function intra-mammary, nor how to administer this compound intra-mammary.

C. Claims 1, 4, 5, 8, 9, 11, 12, 15, 21, 23, 72, 74, 75 and 78 are rejected under 35 USC 112, first paragraph, because the specification, while being enabling for the antagonist and agonist assays on pages 10, 13 and 15 of the specification, does not reasonably provide enablement for all agonist and antagonistic assays. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The breadth of the claims is excessive with regard to Applicants claiming any peptide at least 12 residues in length of SEQ ID NO:11 which is an antagonist in any assay as well as exerting any agonist effect, as seen in claim 74. Applicants have only provided guidance and working examples of two assays for determining antagonists – pages 10 and 13 of the specification and one assay for determining agonist activity (page 15). Applicants have not provided any guidance or working examples of any other assays to determine agonist or antagonist compounds of SEQ ID NO:11, nor would it be predictable to the artisan what assays would be able to be used to determine agonist and antagonist properties of compounds of SEQ ID NO:11.

Therefore, due to the excessive breadth of the claims regarding the use of any agonist and antagonist assays, along with the lack of guidance and working examples of assays other than those on pages 10, 13 and 15 of the specification as well as the unpredictability to the artisan as to which assays can be used to determine agonists and antagonists, especially in view of the concentration range in claim 74, leads the Examiner to hold that undue experimentation would be required to practice the claimed invention.

Art Unit: 1647

5. Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are indefinite since it is unclear what the intent is of culturing cells in the presence of the compounds of claim 1.

B. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how to produce the claimed medicament.

6. Conclusion

A. No claim is allowable.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
October 18, 2003


ROBERT LANDSMAN
PATENT EXAMINER